



## **CIRCULITE® RECEIVES APPROVAL TO BEGIN CE MARK TRIAL FOR SYNERGY® IC CIRCULATORY SUPPORT SYSTEM**

SYNERGY IC System Specifically Designed for Interventional Cardiologist Cannula Deployment

TEANECK, NJ (May 15, 2013) – [CircuLite®, Inc.](#) today announced that it has received approval from the Federal Agency for Medicines and Health Products in Belgium to commence the CE Mark trial of the SYNERGY® IC Circulatory Support System, the first mechanical support system that does not require major surgery. The SYNERGY IC System is based on the surgical [SYNERGY® Circulatory Support System](#) – the world's smallest commercially available circulatory support pump - which is designed to treat ambulatory chronic heart failure patients (INTERMACS ≥4).

While the SYNERGY IC Circulatory Support System uses the same superficially placed micro-pump platform as the surgical system, it is the first implantable circulatory support system whose Inflow Cannula is designed to be implanted by a cardiologist using standard interventional techniques. The procedure is designed to further reduce the invasiveness of implantation, and thereby reduce the rate and severity of adverse events.

"Imagine being able to implant a permanent mechanical support device in a patient with chronic heart failure without major surgery," said Daniel Burkhoff, MD, PhD, Chief Medical Officer of CircuLite and Adjunct Associate Professor of Medicine at Columbia University Medical School. "If successful, this approach will usher in a new era in mechanical circulatory support, much the same way TAVR did for aortic valve replacement."

The multi-center CE Mark trial will enroll up to 20 patients, starting in Belgium and expanding to two additional European clinical sites. Clinical status, end organ function, exercise tolerance, functional capacity and quality of life will be assessed post-implantation. Patient screening has commenced at the University Hospitals Leuven, Belgium.

"With an even less invasive, interventional procedure performed in the cath lab or hybrid OR, we will be making the SYNERGY system more accessible, more convenient and potentially safer for patients," said Paul Southworth, Chief Executive Officer of CircuLite.

Dr. Burkhoff will be presenting an abstract on The SYNERGY IC System at EuroPCR in the Cardiovascular Innovation Pipeline – Novel Interventional Approaches for Heart Failure session, to be held on Thursday, May 23, 2013 from 15:40 to 16:40 in Room 352A of the Palais des Congr s in Paris.

The surgical SYNERGY System received [CE Mark](#) in September 2012 and is commercially available in Europe.

### **[About the SYNERGY® Circulatory Support System](#)**

The SYNERGY Circulatory Support System is a micro-blood pump that provides up to 4.25 liters of blood per

minute and reduces the heart's workload, while improving blood flow to vital organs. It is designed to reverse heart failure in chronic heart failure patients who are not yet inotrope-dependent (INTERMACS  $\geq 4$ ). The SYNERGY System draws blood from the left atrium and the micro-pump is placed in a pacemaker-like pocket and attached to the subclavian artery. The system is designed to be a less invasive implant procedure and intended to reduce the risks associated with implantation of long-term circulatory support. In addition, SYNERGY is intended to reduce rehospitalizations associated with heart failure symptoms.

### About CircuLite®

CircuLite is developing disruptive solutions to improve the treatment of heart failure. The Company's technologies work in conjunction with the heart to enhance clinical outcomes and improve quality of life. SYNERGY, which received CE Mark in 2012, features the smallest surgically-implanted blood pump for long-term use in ambulatory chronic heart failure patients not responding to optimal medical treatment. The company is developing a portfolio of minimally-invasive systems based on its proprietary micro-pump platform, including an interventional cardiology system, a right-heart system and a pediatric system. For more information, visit our website at [www.circulite.net](http://www.circulite.net).

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